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Applicant:

Jay Skeen

Serial No: 10/047,081

Filing Date:

January 15, 2002

For:

IMPLANTABLE WIRELESS SENSOR FOR PRESURE MEASUREMENT WITHIN THE HEART

Enclosures:

(1) Supplemental Amendment (7 pages);

(2) Petition for Extension of Time (1 page) w/fee check in the amount of \$210.00;

(3) Acknowledgement Postcard.

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Attorney Docket: 501159.20501 (24228.03)

## THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Jay Skeen

Examiner:

J.M. Ludlow

Serial No.:

10/047,081

Group Art Unit:

1743

Filed:

January 15, 2002

Confirmation No.: 7457

For:

IMPLANTABLE WIRELESS SENSOR FOR PRESSURE

MEASUREMENT WITHIN THE HEART

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## SUPPLEMENTARY AMENDMENT

SIR:

In further response to the Office Action dated March 19, 2003, Applicant has the following additional comments:

In the Office Action, Claims 1, 15, 18 and 20 were rejected under 35 U.S.C. §102(b) as being anticipated by Goodman, U.S. Patent No. 5,343,909 ("Goodman"). The Examiner maintains that Goodman teaches a pipette tip having tubular body 37, 65 in pressure communication with tips 23 via membrane 19, which can be provided in pairs (Figure 1) or fours (Figures 20, 21); that the tips are structurally capable of fitting together in well 25 or separately in wells 57 of suitable size; and that, Claim 1 has been interpreted to agree with Claim 15, i.e., to have a membrane

Claims 1, 4, 14, and 18-20 have rejected under 35 U.S.C §102(e) as being anticipated by Treptow et al., U.S. Patent No. 5,844,686 ("Treptow"). The Examiner maintains that Treptow teaches a pipette tip having two conical tips extending from a single tubular body for receiving sample and reagent separately into the same pipette tip (Figure 11; col. 5, lines 31-33); that no membrane is shown in Figure 11; that an opening 13 is provided, which is structurally capable of attaching to different pipettes with different plunger lengths; and that the tips are structurally capable of fitting together or separately in wells of suitable size.

Claims 1, 3-4, 14, and 18-20 have been rejected under 35 U.S.C §103(a) as being unpatentable over Treptow as applied to Claims 1, 4, 14, and 18-20 above, and further in view of Goodman. The Examiner maintains that Treptow fails to teach four tips in one pipette tip or explicitly teach fitting all the channels in one well and individual wells; that the teachings of Goodman are given above; that it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide four conical tips on the device of Treptow to simultaneously pipette four reagents into a common tip device as an alternative to two reagents as taught by Goodman; and that with respect to the alternative rejections of Claims 1, 4, 14 and 18-20, it would have been obvious to size the channels of Treptow to fit in a single well and then individual wells to transfer the same fluid to individual wells as taught by Goodman.

Claims 15 and 16 have been rejected under 35 U.S.C §103(a) as being unpatentable over Treptow alone or Treptow and Goodman as applied to Claim 1 above, and further in view of Raybuck, U.S. Patent No. 5,556,598. The Examiner maintains that the primary references fail to teach an oval shaped tip or a filter to prevent contamination; that Raybruck teaches a pipette tip with an oblique opening, which results in an oval cross-section at the opening of the tip (Figure 7) and a filter 18 to prevent aerosol contamination; that it would have been obvious to provide the tip of Treptow or Treptow and Goodman with an oblique opening as taught by Raybuck to prevent sealing of a flat

tip against a flat well bottom as was known in the art; and that it would have further been obvious to provide aerosol filters as taught by Raybuck in the channels to keep aerosols from contaminating the pipetter.

Applicant respectfully traverses the above rejections.

Micro titration plates are standard in biomedical research and in clinical testing labs. These plates are available in 96 well formats, 384 well formats and 1536 well formats, with all having the same external foot print. (The external footprint is the outside dimension of the plate, which are standard shape and size). The Plural Channel Tips of the invention are designed to fit in different variations of plate well and formats. A Plural Channel Tips arrangement fits into a single well of a 96 well format microtitration plate. It will have four channels separated with the proper spacing in a rectangular configuration, as each channel will fit into one of four wells of a 384 well format micro-titration plate. The same is true for a single well of a 384 well formatted micro-titration plate – where the separation of the Plural Channel Tips are properly spaced in a rectangular configuration so each channel fits, individually, into four wells of a 1536 well formatted micro-titration plate. The Plural Channel Tips are configured to also transfer liquid from four wells of a 384 well format micro-titration plate to similar four wells in a different 384 well format micro-titration plate.

The purpose for this rectangular configuration of the invention is to allow four samples or aliquots to be drawn from a single well and dispensed into four different wells or transfer liquid samples from four wells into four other wells. The invention has the following advantages:

- 1. Rectangular liquid dispensing configuration.
- 2. Designed to fit industry standard micro titration plates in 96,384,1536 well format with similar external foot print

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 Variously sized plural channel tips that allow drawing and dispensing liquids into multiple industry standard micro-titration plates

- 4. Within the plural channel tip, internal dimensions of the channels may vary to allow dispensing of various volumes. One of the major advantages is that the liquid drawn up into the plural channel tip will be at the same level in each channel. Therefore, a change in internal dimensions in one of the channels will allow a different volume to be dispensed from that channel.
- 5. Designed to work with existing manual and automated pipetting devices. It does not require special pipettors or vacuum housing.

The Goodman patent concerns sealing the tops of each of the tips (the tips, not the chamber) with a flexible membrane. The Goodman patent also includes the manufacturing process for sealing the membrane at the top of each tip. It requires special vacuum housing or holder and a special pipettor. The plural channel tip is specifically designed to work with **existing** liquid handling equipment – both manual and automated equipment. The accuracy is not dependent upon the flexibility of a membrane.

In Goodman's device, each tip 23 is individually sealed with an elastic membrane 16 and is enclosed in a vacuum housing or holder. The plural channel tip of the inventor is not housed in any special vacuum device or holder. The plural channel tip works in existing liquid handling equipment that is common in biomedical labs. The plural channel tip has no elastic membrane between the channel and the vacuum (air displacement).

Goodman teaches a single elastic membrane attached at the top of each of the channels, each of which is sealed off from the vacuum. The Plural Channel Tips arrangement of the invention works on the concept that the liquid will reach a similar height in each channel naturally, without special vacuum housing. Goodman does not

show a plural channel tip with a single membrane attached at the top of each individual channel. Again, each tip has a membrane seal at the top and requires special vacuum devices not found in biomedical labs.

Goodman's device does not work in existing laboratory equipment.

The Examiner states, with regard to Goodman, that "the tips are structurally capable of fitting together or separately in wells of suitable size...." However, this overlooks the fact that Goodman's patent is based upon a sealing membrane on the top of each tip. Goodman did not show a plural channel tip; rather, he showed a tip array with a sealed membrane at the top of each tip. It is not similar to the invention claimed herein.

With regard to Treptow the Examiner states that "Treptow teaches a pipette tip having two conical tips extending from a single tubular body for receiving sample and reagent separately into the same pipette tip...." Treptow states in the abstract that the pipette tip is being used as a <u>reaction vessel (Cell)</u> for photometer measuring. The Plural Channel Tips arrangement of the invention is not designed to mix separate reagents in the pipette tip; rather, the Plural Channel Tips arrangement is designed to keep the reagents <u>separate</u> in the transfer of liquids.

The short conical pipette tip ends of Treptow are designed to <u>mix</u> two or more reagents or samples and to reflect light signals for photometer measurement readings. As can be seen from the design shown in Figure 11 a generous upper tubular body 4 was designed to allow for mixing reagents entering the pipette tip from ends 24 and 25. This also allows photometric "reading" room for the photometer. Element 4 of Figure 11 is a single mixing and reading chamber.

In contradistinction, the tips of the present invention, are separated to prevent mixing, the tip has no mixing area and is designed for liquid dispensing. The upper tubular body of the present invention is minimized to increase a larger area for the transferring of liquids, being sure <u>not to mix</u> or contaminate individual channels with one another.

Treptow does not disclose describe or claim, a second end of said tubular body having a plurality of spaced, approximately parallel, legs extending away from said tubular body, said plurality of avoiding mixing of contents of individual legs as set forth in amended Claim 1 of the present invention.

The Examiner has rejected claims under 35 U.S.C §103(a) as being unpatentable over Treptow in view of Goodman. In light of the discussion rendered above Applicant asserts that Treptow, Goodman, or a combination of both references do not disclose describe or claim, a second end of said tubular body, having a plurality of spaced, approximately parallel legs extending away from saud tubular body, said plurality of legs avoiding mixing of contents of individual legs as set forth in amended Claim 1 of the present invention.

With regard to the rejection of Claims 15 and 16, the deficiencies of Goodman and Treptow are not overcome by Rayback, regardless of the fact that combination of their three references is inappropriate. Since Claims 15 and 16 have been cancelled, further discussion is not believed necessary.

Applicant believes that the invention described in the amended claims is not disclosed or suggested by the references cited and that the rejections should be withdrawn.

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Claim 2 has been rejected under the judicially created doctrine of obviousnesstype double patenting. Applicant disagrees that this rejection is sound. However, Applicant is willing to consider submission of a terminal disclaimer.

Reconsideration and allowance of the claims herein are respectfully requested.

Respectfully submitted,

February 26, 2004

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